DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-26

July 10, 2000

Sam Cohen, President
City Smoked Fish Company
14440 Wildemere
Detroit, MI. 48238

Dear Cohen:

On January 12 through 25, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 14440 Wildemere in Detroit, Michigan. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) for fish and fishery products and the current Good Manufacturing Practice requirements for foods (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator presented your firm with a Domestic Seafood HACCP Report that presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP requirements.

Your firm is in violation of 21 CFR 123, causing your hot smoked fish products (chubs, whitefish, sable, salmon) and cold smoked salmon to be deemed adulterated under the provisions of 21 USC 342(a)(4) because of the following deficiencies:

1. You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(b). However, you did not have monitoring records to document minimum and/or maximum brine time and minimum salt concentration for the brining critical control point to control *C. botulinum* hazard. This deficiency is a repeat violation from the January 13 and 20, 1998 inspection conducted at your facility.

2. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, you do not have sanitation control records for the following four required items: a) food contact b) cross contamination c) toxic compound and d) employee health.

3. You must take an appropriate corrective action when a deviation from a critical limit occurs, in order to comply with 21 CFR 123.7(a). However, your firm did not take an appropriate corrective action to control *C. botulinum* hazard when you processed [redacted] pounds of hot smoked sable on June 15, 1999 at least [redacted] minutes less than the specified critical time limit at the smoking critical control point.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone 313-226-6260 x 135. If you need further assistance, all technical questions should be directed to either Nicholas L. Majerus, Shellfish Specialist at extension 107 or Sally S. Eberhard, Seafood Monitor at extension 109.

Sincerely,

John P. Dempster

for Raymond V. Mlecko,
Director
Detroit District